Protocol for Meningococcal Containing Vaccines
MenQuadfi®, Menveo®, Bexsero®, Trumenba®, and Penbraya™

1. What's New

A. Meningococcal ABCWY vaccine, Penbraya™, was added as an alternative vaccine option for individuals 10-25 years of age who are intending to receive both the MenACWY and MenB vaccines at the same visit.
B. Menveo® dosage and administration updated for 1 and 2 vial presentations.[4]
C. Menactra® has been removed from the market, all guidance related to Menactra® removed from protocol.

2. Immunization Protocol

A. Administer a 0.5-mL dose, IM, of meningococcal vaccine according to age-appropriate schedules and high-risk conditions.
B. Meningococcal ACWY vaccines are interchangeable when more than one brand is age-appropriate. [1]
C. Meningococcal B vaccines are not interchangeable. All doses of Meningococcal B must be of the same brand of vaccine.[1]
D. The MenACWY and MenB vaccines may be given simultaneously at different sites if indicated. [1] Alternatively, patients intending to receive both MenACWY and MenB vaccines at the same visit may instead receive the MenABCWY vaccine.[7]
E. Meningococcal vaccines can be given with all other routinely recommended vaccines.[2]

3. Vaccine Schedule

MenACWY Vaccines (MenQuadfi®, Menveo®) Schedule for Routine Use, Dose and Route – 0.5-mL, IM		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	11-18 years	
Booster	16-18 years	8 weeks

MenACWY Vaccines (MenQuadfi®, Menveo®) Schedule for High-Risk Persons, Dose and Route – 0.5-mL, IM		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥7 years	
2		8 weeks if 2 doses indicated
Boosters (if person remains at risk)	Aged <7 years at completion of primary series: Single dose at 3 years after primary vaccination and every 5 years thereafter Aged ≥7 years at completion of primary series: Single dose at 5 years after primary vaccination and every 5 years thereafter	

MenB Vaccines (Bexsero®, Trumenba®) Schedule for Healthy Persons*, Dose and Route – 0.5-mL, IM		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	16-23 years	
2		28 days for Bexsero®, 6 months for Trumenba®

*ACIP recommends a MenB series for persons aged 16–23 years (preferred age 16–18 years) on the basis of shared clinical decision-making. See section 5 for guidance.

MenB Vaccines (Bexsero®, Trumenba®) Schedule for High-Risk Persons, Dose and Route – 0.5-mL, IM		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥10 years	
2		28 days
3*		4 months after dose 2
Boosters (if person remains at risk)		Single dose at 1 year after completion of primary vaccination and every 2–3 years thereafter

*Dose 3 applies to Trumenba® only, not needed if dose 2 was administered at least 6 months after dose 1. If dose 3 is administered earlier than 4 months after dose 2, a 4th dose should be administered at least 4 months after dose 3.

MenABCWY Vaccines (Penbraya™) Schedule for Routine Use, Dose and Route – 0.5-mL, IM		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	10-25 years	
2		6 months

*If a patient is receiving MenACWY and MenB vaccines at the same visit, MenABCWY may be given instead. If a patient receives MenABCWY vaccine, which includes Trumenba®, then administer:

- Trumenba® for additional MenB dose(s) when MenACWY is not indicated
- Any MenACWY vaccine when MenB is not indicated

4. Licensed Vaccines

Meningococcal ACWY Conjugate Vaccines				
Product Name	**Vaccine Components**	**Presentation**	**FDA Approved Age Range**	**Thimerosal**
MenACWY-TT[3] (MenQuadfi®)	Neisseria meningitidis serogroup A, C, W, and Y capsular polysaccharide antigens that are individually conjugated to tetanus toxoid protein	0.5-mL single-dose vials	≥2 years	None
MenACWY-CRM[4] (Menveo®)	Neisseria meningitidis serogroup A, C, Y, and W-135 oligosaccharides conjugated individually to Corynebacterium diphtheriae CRM protein	Single-dose 2 vial presentation (gray and orange caps) that requires reconstitution. 0.5-mL dose once reconstituted	2 months-55 years	None
		0.5-mL single-dose 1 vial presentation (pink cap) that does **not** require reconstitution	10-55 years	None

Meningococcal B Vaccines				
Product Name	**Vaccine Components**	**Presentation**	**FDA Approved Age Range**	**Thimerosal**
MenB-4C (Bexsero®)[5]	Recombinant proteins Neisserial adhesin A (NadA), Neisserial Heparin Binding Antigen (NHBA), and factor H binding protein (fHbp)	0.5-mL prefilled syringes	10-25 years	None
MenB-fHbp (Trumenba®)[6]	Two recombinant lipidated factor H binding protein (fHbp) variants from N. meningitidis serogroup B, one from fHbp subfamily A and one from subfamily B (A05 and B01, respectively)	0.5-mL prefilled syringes	10-25 years	None
Meningococcal ABCWY Vaccine				
Product Name	**Vaccine Components**	**Presentation**	**FDA Approved Age Range**	**Thimerosal**
MenABCWY (Penbraya™)[7]	Neisseria meningitidis serogroup A, C, W, and Y polysaccharides conjugated to tetatnus toxoid and two recombinant lipidated factor H binding protein (fHbp) variants from N. meningitidis serogroup B, one from fHbp subfamily A and one from subfamily B (A05 and B01, respectively)	0.5-mL single-dose diluent in prefilled syringe and vial with lyophilized antigen	10-25 years	None

5. Recommendations for Use

A. Routine use of Meningococcal ACWY vaccine[1]

a. All adolescents 11–18 years of age without contraindications. Preferred age for dose one is 11-12 years with a booster dose at age 16 years. Catch-up vaccination age for dose one is 13–15 years with a booster dose at age 16–18 years. If series started at age 16 or older, no booster dose is indicated.

i. Children who received MenACWY at age 10 years do not need an additional dose at age 11–12 years but should receive the booster dose at age 16 years. Children who received MenACWY before age 10 years and with no ongoing risk for meningococcal disease for which boosters are recommended should still receive MenACWY according to the recommended adolescent schedule.

b. Unvaccinated or under vaccinated first-year college students living in residence halls. One dose may be administered to persons 19-21 years who have not received a dose after their 16th birthday. Boosters are not routinely recommended unless there is another indication.

c. Military recruits 19-21 years of age who have not received a dose after their 16th birthday. Administer one dose with booster every 5 years based on assignment. Vaccine recommendations for military personnel are made by the U.S. Department of Defense.

d. Booster doses for previously vaccinated persons who become or remain at increased risk. At 3 or 5 years after primary vaccination depending on age at last dose and every 5 years thereafter.

B. Use of Meningococcal ACWY vaccine in high-risk persons[1]

a. Persons with complement component deficiency or who are taking complement inhibitor medications, with anatomical or functional asplenia, or with HIV should receive 2 doses 8 weeks apart.

b. Microbiologists routinely exposed to isolates of Neisseria meningitidis, persons at increased risk during an outbreak (e.g., in community or organizational settings, and among men who have sex with men [MSM]), and persons who travel to or live in countries in which meningococcal disease is hyperendemic or epidemic, particularly the meningitis belt in sub-Saharan Africa, should receive 1 dose.

i. Vaccination is required for entry for persons traveling to Saudi Arabia for the Hajj and Umrah pilgrimages.

C. Use of Meningococcal B vaccine in healthy persons[1]

a. Vaccination of adolescents and young adults aged 16–23 years with a 2-dose MenB series on the basis of shared clinical decision-making. MenB vaccination is not routinely recommended for all adolescents. Instead, ACIP recommends a MenB series for persons aged 16–23 years (preferred age 16–18 years) on the basis of shared clinical decision-making. Shared clinical decision-making refers to an individually based vaccine recommendation informed by a decision-making process between the health care provider and the patient or parent/guardian. Pharmacists can engage in shared clinical decision making to discuss MenB vaccination with persons aged 16-23 years who are most likely to benefit.

i. Pharmacists are authorized to administer MenB vaccine if the following risk factor is present: College students, especially those who are freshmen, attend a 4-year university, live in on-campus housing, or participate in sororities and fraternities

D. Use of Meningococcal B vaccine in high-risk persons[1]

a. Persons with persistent complement component deficiencies or who are taking complement inhibitor medications, with anatomic or functional asplenia, and Microbiologists routinely exposed to isolates of *Neisseria meningitidis* should receive the 2-dose series of Bexsero® or the 3-dose series of Trumenba®.

i. A single booster dose for previously vaccinated persons who remain at increased risk should be given at 1 year after completion of primary vaccination and every 2-3 years thereafter.

b. Persons at increased risk during an outbreak (e.g., in community or organizational settings, and among MSM should receive the 2-dose series of Bexsero® or the 3-dose series of Trumenba®.
   i. A single booster dose for previously vaccinated persons and identified at increased risk during an outbreak should be given if ≥1 year after completion of primary series (a ≥ 6-month interval might also be considered by public health).

E. Use of Meningococcal ABCWY vaccine
   a. If a patient is receiving MenACWY and MenB vaccines at the same visit, MenABCWY may be given instead.
      i. If a patient receives MenABCWY vaccine, which includes Trumenba®, then administer:
         1. Trumenba® for additional MenB dose(s) when MenACWY is not indicated
         2. Any MenACWY vaccine when MenB is not indicated
      ii. The minimum interval between MenABCWY doses is 6 months.
   b. People with prolonged increased risk for serogroup A, C, W, or Y and B meningococcal disease need regular boosters. However, the recommended interval between doses varies by age and vaccine type. MenABCWY vaccine can be used only when both MenACWY and MenB vaccines are indicated at the same visit. Otherwise, MenACWY and MenB vaccines should be given separately as appropriate.

6. Contraindications

A. Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component.[3-7]

Vaccine	Contains
MenACWY-TT – MenQuadfi®	sodium chloride, sodium acetate, formaldehyde, tetanus toxoid
MenACWY-CRM - Menveo®	formaldehyde, CRM197 protein
MenB-4C - Bexsero®	aluminum hydroxide, sodium chloride, histidine, sucrose, kanamycin
MenB-FHbp - Trumenba®	polysorbate 80, aluminum phosphate, histidine buffered saline
MenABCWY- Penbrayra™	L-histidine, trometamol, sucrose, aluminum phosphate, sodium chloride, and polysorbate 80

7. Warnings and Precautions[3-6]

A. N/A

8. Other Considerations

A. Immunocompromised: individuals with altered immunocompetence may have reduced immune responses.[3-6]
B. Pregnant and lactating women should receive MenACWY vaccine if indicated. However, due to a lack of data, vaccination with MenB should be deferred unless the woman is at increased risk and, after consultation with her health care provider, the benefits of vaccination are considered to outweigh the potential risks.[1]

C. Lactation: It is not known whether meningococcal vaccines are excreted in human milk. Use with caution in nursing mothers.[1]
D. MenACWY meningococcal vaccines will stimulate protection only against infections caused by organisms from serogroups A, C, Y and W meningococci. They are not protective against serogroup B meningococci.[5,6]
E. Meningococcal vaccine is recommended 2 weeks before or ≥2 weeks after splenectomy surgery for persons ≥7years of age.[1]
F. Immunization with MenQuadfi® or Penbraya™ does not substitute for routine tetanus immunization.[3,7]

9. Side Effects and Adverse Reactions[3-7]

MenACWY Vaccines	
Adverse Event	**Frequency**
Low-grade fever, headache, redness at injection site, dizziness	Up to 40%
Grade 3 - fever, headache, redness at injection site, dizziness	Up to 3%
MenB Vaccines	
Adverse Event	**Frequency**
Headache, fatigue, redness at injection site	Up to 51%
Pain at injection site	Up to 26%
Chills, joint pain	Up to 20%
Fever	Up to 2.5%
MenABCWY Vaccine	
Adverse Event	**Frequency**
Pain at injection site	Up to 89%
Fatigue	Up to 52%
Headache	Up to 47%
Muscle pain	Up to 26%
Injection site redness	Up to 26%
Injection site swelling	Up to 25%
Joint pain	Up to 20%
Chills	Up to 20%

10. Storage and Handling

A. Store medications according to OAR 855-041-1036.
B. All clinics and pharmacies enrolled with the Vaccines for Children (VFC) Program must immediately report any storage and handling deviations to the Oregon Immunization Program at 971-673-4VFC (4823).

Vaccine	Temp	Storage Issues	Notes
MenQuadfi®[3]	Store at 2°to 8°C (36° to 46°F)	Protect from light. Do not use if vaccine has been frozen.	
Menveo®[4] and diluent			After reconstitution, administer Menveo® immediately or store between 2°C and 25°C (36°F and 77°F) for up

			to 8 hours. Shake well before using. Discard reconstituted vaccine if it has been frozen or not used within 8 hours.
Bexsero®[5] and Trumenba®[6]			
Penbraya™[7]		During storage, a white deposit and clear supernatant may be observed in the prefilled syringe containing the MenB Component. Store the carton horizontally to minimize the time necessary to resuspend the MenB Component. Do not freeze. Discard if the carton has been frozen	After reconstitution, administer PENBRAYA immediately or store between 2°C and 30°C (36°F and 86°F) and use within 4 hours. Do not freeze.

10. References

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11. Appendix

A. Centers for Disease Control and Prevention (CDC). Shared Clinical Decision-Making for Meningococcal B Vaccination in Adolescents and Adults: Job Aid for Healthcare Professionals. Atlanta, GA: US Department of Health and Human Services, CDC; 2022. https://www.cdc.gov/vaccines/hcp/admin/downloads/ISD-job-aid-SCDM-mening-b-shared-clinical-decision-making.pdf